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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,093	02/02/2004	Marcia K. Wolf	034047.033.4	6121
7590	12/28/2005		EXAMINER	
Office of the Staff Judge Advocate U.S. Army Medical Research and Materiel Command ATTN: MCMR-JA (Ms. Elizabeth Arwine) 504 Scott Street Fort Detrick, MD 21702-5012			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 12/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/768,093	WOLF ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 February 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 8-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 8-30 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

Claims 8-30 are pending.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 8-9, 12-15, 29-30 , drawn to a plurality of independent and distinct nucleic acids defined by SEQ ID NOs, vector, host cell , classified in class 536, subclass 23.7.
  - II. Claims 10-11, 25-28, drawn to a plurality of independent and distinct polypeptides defined by SEQ ID NOs, classified in class 530, subclass 350.
  - III. Claims 16-24, drawn to methods of inducing an antigenic response to one or more proteins or host cells that express the proteins, classified in class 424, subclass 234.1.
2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The inventions are distinct from each other because of the following reasons:

1. The invention of group II (proteins) is distinct from the invention of group I (nucleic acid molecules) because it is drawn to materially different compositions that require non-coextensive areas of search and consideration. For example, the proteins of the invention of Group II may be isolated from natural sources and are not necessarily defined by the DNAs that encode them.

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2. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, specifically the isolated nucleic acid molecules may be used in methods of detecting infection caused by E.coli, in methods of making a recombinantly produced polypeptide, or in methods of inducing an immune response after transforming a host cell to express the nucleic acid.

3. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product , specifically in methods of detecting antibodies, in methods of purifying antibodies, as well as in methods of generating a vaccine .

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. In addition to the preceding restriction requirement, upon the election of Group I, the following additional election would be required:

Claims 8-9, 12-15, 29-30 are drawn to isolated nucleic acid molecules that independent and distinct as they structurally differ one from the other and encode proteins of functionally different biological activity. Each nucleic acid is represented by a different SEQ ID NO, specifically SEQ ID NO 1, 4, or encodes SEQ ID NO 5,6,7,8,9 or 10. Applicant is required to select a single sequence for examination. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and because the searches required for the separate groups of inventions are non-coextensive, restriction for examination purposes as indicated is proper.

8. In addition to the preceding restriction requirement, upon the election of Group II, the following additional election would be required:

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6. Group II, Claims 10-11, 25-28 are drawn to a plurality of disclosed patentably distinct products comprising materially different proteins. Should the inventions of Group II be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product (SEQ ID NO 5 or 6 or 7 or 8 or 9 or 10 or combination), even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

9. In addition to the preceding restriction requirement, upon the election of Group III, Claims 16-24, the following additional election would be required. Group III is directed to a plurality of independent and distinct methods of inducing an antigenic response in a subject based upon the structurally and functionally distinct polypeptides or host cell that comprises and expresses a structurally and functionally distinct nucleic acid molecule, each administered composition being defined to be distinct based upon a SEQ ID NO, specifically SEQ ID NO 1, or 4 or 5 or 6 or 7 or 8 or 9 or 10).

10. Should applicant traverse on the ground that the proteins represented by structurally different SEQ ID NOs are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
December 15, 2005

*Lynette R. F. Smith*  
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